AIN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

CIVIL ACTION FILE NO.: 5:19-CV-505

AQUESTIVE THERAPEUTICS, INC.,	)
Plaintiff	)
	)
v.	)
	)
BIODELIVERY SCIENCES INTERNATIONAL, INC.,	)
Defendant	)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Aquestive Therapeutics, Inc. ("Aquestive"), by its undersigned attorneys, hereby files this Complaint against Defendant BioDelivery Sciences International, Inc. ("BDSI") and alleges as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 8,765,167 ("the '167 patent"), arising under the patent laws of the United States, Title 35 of the United States Code.

2. Defendant BDSI markets and sells BELBUCA® (buprenorphine) buccal film ("BELBUCA"), which is a pharmaceutical drug product that infringes at least claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118 of the '167 patent.

BACKGROUND

3. BDSI submitted a New Drug Application ("NDA") under 21 U.S.C. § 355(b)(2) (NDA No. 207932), seeking approval to manufacture, market and sell BELBUCA throughout the United States, including in this Judicial District. BDSI's NDA was approved by the Food and Drug Administration ("FDA") on October 23, 2015, for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. According to its own website, BDSI markets and sells its BELBUCA product nationwide.

4. BDSI has had knowledge of the '167 patent since at least October of 2014. On September 22, 2014, Aquestive (together with Reckitt Benckiser Pharmaceuticals, Inc. and RB Pharmaceuticals Limited) sued BDSI for infringement of the '167 patent for BDSI's infringing Bunavail™ film product. The complaint was served on October 13, 2014. On October 28, 2014, BDSI filed four separate petitions for inter partes review ("IPR") of the '167 patent with the Patent Trial and Appeal Board ("PTAB"). In particular, in IPR2014-00167, BDSI challenged claims 13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118 of the '167 patent. The PTAB declined to institute BDSI's petition on all of these claims, finding that BDSI could not "establish[] a reasonable likelihood that it would prevail as to its challenges of claims 13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118 of the '167 patent on any of the grounds presented in the Petition." IPR2014-00167, Paper No. 6, p.31 (May 20, 2015 Decision Denying Institution).

5. With full knowledge of the '167 patent, and despite having been previously sued for other products that infringe the '167 patent, BDSI has willfully launched BELBUCA, a new product that infringes the '167 patent. In this case, however, BDSI is subject to the one-year statutory bar under 35 U.S.C. § 315(b); and consequently, BDSI cannot obtain an inter partes review of claims 13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118 of the '167 patent.

THE PARTIES

6. Plaintiff Aquestive Therapeutics, Inc. is a Delaware corporation having a principal place of business at 30 Technology Drive, Warren, New Jersey 07059.

7. Upon information and belief, Defendant BDSI is a Delaware corporation having a principal place of business at 4131 ParkLake Ave., Suite 225, Raleigh, North Carolina, 27612.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b) at least because BDSI has committed and continues to commit acts of patent infringement in this District and has a regular and established place of business in the Eastern District of North Carolina.

10. This Court has personal jurisdiction over BDSI at least because of, *inter alia*, BDSI's principal place of business in North Carolina; BDSI's continuous and systematic contacts with corporate entities within this Judicial District; BDSI's

purposeful availment of the benefits and protections of the laws of North Carolina; and BDSI's marketing and sales activities in this Judicial District, including but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products—including BELBUCA—to residents of this Judicial District.

THE '167 PATENT

11. Aquestive is a specialty pharmaceutical company that uses its proprietary PharmFilm® technology to deliver drugs in films. Through years of research and development, Aquestive has obtained over 200 patents and several FDA approvals.

12. On July 1, 2014, the '167 patent, entitled "Uniform Films for Rapid-dissolve Dosage Form Incorporating Anti-tacking Compositions," was duly and legally issued to inventors Garry L. Myers, Pradeep Sanghvi, Andrew Philip Verrall, Vimala Francis, and Laura Moss. That patent was assigned to Aquestive. A true and correct copy of the '167 patent is attached as Exhibit A.

13. The '167 patent generally relates to rapidly dissolving films that incorporate anti-tacking agents and/or that contain an active component—such as a drug—that is evenly distributed throughout the film. *See*, *e.g.*, Exhibit A at Abstract. Oral films have several advantages as alternatives to tablets, pills, and the like. *See*, *e.g.*, *id.* at 1:26-47.

14. The inventors of the '167 patent conceived of pioneering improvements in the making of films, improvements that enable uniform distribution of components

therein and that prevent undesired aggregations of components in the final film product. Their improvements are set forth in the claims of the '167 patent. For example, Claim 95 recites:

> An oral film for delivery of a desired amount of an active component comprising:
>
> an ingestible, water-soluble polymer matrix comprising a polymer selected from the group consisting of hydroxyethylcellulose, hydroxypropylcellulose and carboxymethyl cellulose and combinations thereof;
>
> at least one anti-tacking agent comprising sodium benzoate;
>
> a substantially uniform distribution of said desired amount of said active component within said polymer matrix,
>
> wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof,
>
> said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active in place within said matrix and maintain said substantially uniform distribution;
>
> wherein said film is self-supporting and the active component is substantially uniformly distributed, whereby said substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component.

15. Aquestive presently, and during all relevant times, owns all rights, title, and interest to the '167 patent, including the right to sue and to recover for any current or past infringement of that patent.

16. On January 13, 2017, Aquestive filed a complaint in the United States District Court for the District of New Jersey against BDSI for infringement of the '167 patent by BDSI's BELBUCA product. After the case was transferred to this Judicial District, BDSI filed a motion to dismiss the Complaint, which was granted on August 6, 2019. As a result, Aquestive's Complaint was dismissed without prejudice. *See Aquestive Therapeutics, Inc. v. BioDelivery Sciences International, Inc.*, Civil Action No. 5:18-cv-514-D, Dkt. 99 (Aug. 6, 2019) (Dever, J.). As detailed herein, the instant Complaint for Patent Infringement explains the details, as currently known to Aquestive, of how the features of BDSI's BELBUCA product infringe the claims of the '167 patent.

BDSI'S INFRINGING BELBUCA PRODUCT

17. BDSI makes, or directs the making of, BELBUCA. From January 6, 2012, through January 6, 2017, BDSI exclusively licensed to a third party all right to develop and commercialize BELBUCA in the United States. In December 2016, BDSI and the third party entered into an agreement effective January 6, 2017 terminating the BELBUCA license, and all rights to develop and commercialize BELBUCA reverted back to BDSI. *See* Exhibit B, October 31, 2017 Declaration of Mark Sirgo, Civil Action No. 1:17-cv-01307-MSG, Dkt. 49 (Oct. 31, 2017).

18. BDSI directs all development, marketing, and promotional activities relating to BELBUCA from its headquarters in Raleigh, North Carolina. *See id.*

19. BDSI currently markets, sells, and offers for sale BELBUCA in the United States, for the management of pain severe enough to require daily, around-

the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

20. BELBUCA uses BDSI's BioErodible MucoAdhesive ("BEMA") technology which "consists of a small, bioerodible polymer film for application to the mucosal membranes (inner lining of cheek)." *See* Exhibit C (BDSI BEMA webpage).

21. BELBUCA is a buccal film that provides transmucosal delivery of buprenorphine hydrochloride, a partial opioid agonist. *See* Exhibit D, FDA Prescribing Information at 25.

22. BELBUCA buccal film is available in 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, and 900 mcg dosage strengths. *See* Exhibit D, FDA Prescribing Information at 1.

23. The strength of each BELBUCA buccal film is dependent on the buprenorphine concentration in the formulation and the surface area of the film. *See id*. at 25. The film size and strength for each dosage is listed in the table below. *Id*.

Table 6: BELBUCA Identifier & Size

Buprenorphine Strength (mcg)	BELBUCA Identifier	Film Size (cm^2)
75	E0	1.215
150	E1	2.431
300	E3	0.934
450	E4	1.400
600	E6	1.867
750	E7	2.334
900	E9	2.801

24. The active ingredient in BELBUCA is buprenorphine hydrochloride. *Id*. BELBUCA also contains carboxymethylcellulose sodium USP, citric acid anhydrous USP, hydroxyethylcellulose NF, hydroxypropylcellulose NF, methylparaben NF,

monobasic sodium phosphate anhydrous USP, peppermint oil NF, polycarbophil USP, propylene glycol USP, propylparaben NF, sodium benzoate NF, sodium hydroxide NF, saccharin sodium NF, titanium dioxide USP, vitamin E acetate USP, yellow iron oxide, purified water USP, and TekPrintTM SW-9008 black ink (shellac NF, black iron oxide NF). *Id.*

25. The FDA's Approved Drug Products with Equivalence Evaluations (commonly known as the Orange Book) listing for BELBUCA identifies four patents, including United States Patent Nos. 8,147,866 ("the '866 patent"), 9,655,843 ("the '843 patent"), and 9,901,539 ("the '539 patent"), all of which are assigned to BDSI. True and correct copies of the '866 patent, the '843 patent, and the '539 patent are attached hereto as Exhibits E, F, and G.

26. The '866 and '843 patents describe manufacturing processes for films containing buprenorphine, including mixing the ingredients for a backing layer (Exhibit E at 19:21-39; Exhibit F at 19:50-20:2), mixing the ingredients for a mucoadhesive layer (Exhibit E at 19:40-20:3; Exhibit F at 20:3-34), and the following casting and drying procedures (Exhibit E at 20:4-13; Exhibit F at 20:35-44):

> The layers were cast in series onto a St. Gobain polyester liner. First, the backing layer was cast using a knife-on-a-blade coating method. The backing layer was then cured in a continuous oven at about 65 to 95° C. and dried. After two coating and drying iterations, an approximately 8 mil (203 to 213 micrometers) thick backing layer is obtained. Subsequently, the mucoadhesive polymeric diffusion environment was cast onto the backing layer, cured in an oven at about 65 to 95° C. and dried. The devices were then die-cut by kiss-cut method and removed from the casting surface.

27. The ’866 and ’843 patents further describe the ingredients used in the films, including that the films contain sodium benzoate in an amount equal to “about 0.06% total formulation, by weight.” Exhibit E at 19:44; Exhibit F at 20:7-8.

28. The ’866 and ’843 patents further describe the use of polymers to slow or stop the flux of medicament in the films such that “there is typically not free flux of the medicament in all directions” (Exhibit E at 6:33-49; Exhibit F at 6:48-64), and describes that the flux of medicament occurs only once the film is applied to mucosa (*see, e.g.*, Exhibit E at 6:40-45 and Exhibit F at 6:55-60 (“Upon mucoadministration, a gradient is created between the mucoadhesive polymeric diffusion environment and the mucosa, and the medicament flows from the mucoadhesive polymeric diffusion environment, substantially in one direction towards the mucosa.”); Exhibit E at 15:24-27 and Exhibit F at 15:50-53 (“dissolution or erosion of the barrier environment and/or backing layer primarily controls the directionality of medicament flow from the device of the present invention after application to the mucosa”).

29. The ’539 patent describes the manufacturing process for BEMA films containing buprenorphine, including mixing the ingredients for the mucoadhesive layer (Exhibit G at 9:48-10:8), mixing the ingredients for the backing layer (Exhibit G at 10:9-27), and the following casting and drying procedures (Exhibit G at 10:28-38):

> The layers are cast in series onto a St. Gobain polyester liner. First, the backing layer is cast using a knife-on-a-blade coating method. The backing layer is then cured in a continuous oven at about 65° C. to 95° C. and dried. After two coating and drying iterations, an approximately 8 mil (203 to 213 micrometers) thick backing layer is obtained.

> Subsequently, the mucoadhesive polymeric diffusion environment is cast onto the backing layer, cured in an oven at about 65° C. to 95° C. and dried. The devices are then die-cut by kiss-cut method and removed from the casting surface.

30. The ’539 patent further describes the ingredients used in the BEMA films, including that the BEMA films contain sodium benzoate in an amount equal to “about 0.5% total formulation, by dry weight.” Exhibit G at 9:52.

31. The ’539 patent further describes the use of polymers to slow or reduce the flux of medicament in BEMA films such that only “[u]pon oral mucosal application, a gradient is created between the mucoadhesive polymeric diffusion environment and the mucose, and the medicament flows from the mucoadhesive polymeric diffusion environment, substantially in one direction towards the mucosa, until the backing layer dissolves.” Exhibit G at 5:1-33.

COUNT 1:
Infringement of the ’167 Patent

32. Aquestive incorporates each of the preceding paragraphs 1-31 as if fully set forth herein.

33. BDSI has infringed, and continues to infringe the ’167 patent by making, using, offering to sell, and/or selling within the United States, products that practice the inventions of the ’167 patent, including, but not limited to BDSI’s BELBUCA buccal film. BDSI’s BELBUCA buccal film literally infringe at least the following valid and enforceable claims of the ’167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118.

34. More specifically, BDSI's BELBUCA buccal film satisfies all elements of Claim 13 of the '167 patent as follows:

a. Claim 13 recites "[a]n oral film for delivery of a desired amount of an active component comprising."
   i. Regardless of whether the preamble is limiting, BDSI's BELBUCA buccal film literally infringes this limitation.
   ii. BDSI's BELBUCA buccal film "is for oral buccal use." *See* FDA Prescribing Information at 4.
   iii. BDSI's BELBUCA buccal film "provides transmucosal delivery of buprenorphine hydrochloride." *See* FDA Prescribing Information at 25.
   iv. BDSI's BELBUCA buccal film contains buprenorphine hydrochloride as the active ingredient. *See* FDA Prescribing Information at 25.

b. Claim 13 further recites "an ingestible, water-soluble polymer matrix comprising at least one polymer selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, carboxymethyl cellulose, polyethylene oxide and combinations thereof;"
   i. BDSI's BELBUCA buccal film literally infringes this limitation.
   ii. BDSI's BELBUCA buccal film uses BDSI's BEMA "delivery technology comprised of flexible, water soluble polymeric film." *See* Exhibit H, FDA Chemistry Review at 101.
   iii. BDSI's BELBUCA buccal film contains hydroxyethylcellulose NF, hydroxypropylcellulose NF, and carboxymethylcellulose sodium USP. *See* FDA Prescribing Information at 25.

c. Claim 13 further recites "a substantially uniform distribution of said desired amount of said active component within said polymer

matrix, wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active in place within said matrix and maintain said substantially uniform distribution;"

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film contains buprenorphine hydrochloride as the active ingredient. *See* FDA Prescribing Information at 25.

iii. BDSI's BELBUCA buccal film uses BDSI's BEMA "delivery technology comprised of flexible, water soluble polymeric film." *See* Exhibit H, FDA Chemistry Review at 101.

iv. BDSI's BELBUCA buccal film contains a substantially uniform distribution of buprenorphine hydrochloride within the polymer matrix at least because, in approving BELBUCA, the FDA assessed the content uniformity of BELBUCA and found it sufficiently uniform. *See, e.g.*, Exhibit H, FDA Chemistry Review at 6.

v. At least as described in paragraphs 26 and 29 above, BDSI's BELBUCA buccal film is formed using a manufacturing process which involves mixing the ingredients together to make a flowable wet blend, and then casting the viscoelastic, wet blend of ingredients, the film matrix, onto a carrier which travels through an oven to dry the film into a sheet which is then cut into individual units, the specific details of which Aquestive has a good faith basis to believe will be shown by further discovery.

vi. At least as described in paragraphs 26, 28, 29, and 31 above, BDSI's BELBUCA buccal film manufacturing process maintains a high level of drug content uniformity by using a controlled drying process, one aspect of which is to form a polymeric matrix and lock the active component in place so that it minimizes migration so that it does not result in a disuniform film, the specific details of which Aquestive has a good faith basis to believe will be shown by further discovery.

d. Claim 13 further recites "an anti-tacking agent selected from the group consisting of Vitamin E, Vitamin E TPGS, and sodium benzoate, wherein said tacking agent is present in amounts of about 0.01% to about 20% by weight of said film."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film contains sodium benzoate NF. *See* FDA Prescribing Information at 25.

iii. At least as described in paragraphs 27 and 30 above, BDSI's BELBUCA buccal film contains sodium benzoate NF in amount of about 0.01% to about 20% by weight of the film, the specific amount of which Aquestive has a good faith basis to believe will be shown by further discovery.

35. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 33 of the '167 patent as follows:

a. Claim 33 recites "[t]he film of claim 13, wherein said at least one polymer is hydroxyethyl cellulose."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 34, above.

iii. BDSI's BELBUCA buccal film contains hydroxyethylcellulose NF. *See* FDA Prescribing Information at 25.

36. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 39 of the '167 patent as follows:

a. Claim 39 recites "[t]he film of claim 13, wherein said at least one polymer is carboxymethyl cellulose."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 34, above.

iii. BDSI's BELBUCA buccal film contains carboxymethylcellulose sodium USP. *See* FDA Prescribing Information at 25.

37. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 45 of the '167 patent as follows:

a. Claim 45 recites "[t]he film of claim 13, further comprising a buffer."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 34, above.

iii. BDSI's BELBUCA buccal film contains monobasic sodium phosphate anhydrous USP and sodium hydroxide NF. *See* FDA Prescribing Information at 25.

38. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 52 of the '167 patent as follows:

a. Claim 52 recites "[t]he film of claim 13, further comprising a sweetener."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 34, above.

iii. BDSI's BELBUCA buccal film contains saccharin sodium NF. *See* FDA Prescribing Information at 25.

39. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 66 of the '167 patent as follows:

a. Claim 66 recites "[t]he film of claim 13, further comprising a flavoring agent."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 34, above.

iii. BDSI's BELBUCA buccal film contains peppermint oil NF. *See* FDA Prescribing Information at 25.

40. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 73 of the '167 patent as follows:

a. Claim 73 recites "[t]he film of claim 13, further comprising a coloring agent."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 34, above.

iii. BDSI's BELBUCA buccal film contains yellow iron oxide and black iron oxide NF. *See* FDA Prescribing Information at 25.

41. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 83 of the '167 patent as follows:

a. Claim 83 recites "[t]he film of claim 13, wherein the anti-tacking agent comprises sodium benzoate."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 34, above.

iii. BDSI's BELBUCA buccal film contains sodium benzoate NF. *See* FDA Prescribing Information at 25.

42. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 89 of the '167 patent as follows:

a. Claim 89 recites "[t]he film of claim 13, wherein the active component comprises an active selected from the group consisting of an opiate, opiate derivative, analgesic and combinations thereof."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 34, above.

iii. BDSI's BELBUCA buccal film contains buprenorphine hydrochloride. *See* FDA Prescribing Information at 25.

43. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 95 of the '167 patent as follows:

a. Claim 95 recites "[a]n oral film for delivery of a desired amount of an active component comprising:"

i. Regardless of whether the preamble is limiting, BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film "is for oral buccal use." *See* FDA Prescribing Information at 4.

iii. BDSI's BELBUCA buccal film "provides transmucosal delivery of buprenorphine hydrochloride." *See* FDA Prescribing Information at 25.

iv. BDSI's BELBUCA buccal film contains buprenorphine hydrochloride as the active ingredient. *See* FDA Prescribing Information at 25.

b. Claim 95 further recites "an ingestible, water-soluble polymer matrix comprising a polymer selected from the group consisting of hydroxyethyl cellulose, hydroxypropylcellulose and carboxymethyl cellulose and combinations thereof;"

   i. BDSI's BELBUCA buccal film literally infringes this limitation.

   ii. BDSI's BELBUCA buccal film uses BDSI's BEMA "delivery technology comprised of flexible, water soluble polymeric film." *See* Exhibit H, FDA Chemistry Review at 101.

   iii. BDSI's BELBUCA buccal film contains hydroxyethylcellulose NF, hydroxypropylcellulose NF, and carboxymethylcellulose sodium USP. *See* FDA Prescribing Information at 25.

c. Claim 95 further recites "at least one anti-tacking agent comprising sodium benzoate;"

   i. BDSI's BELBUCA buccal film literally infringes this limitation.

   ii. BDSI's BELBUCA buccal film contains sodium benzoate NF. *See* FDA Prescribing Information at 25.

d. Claim 95 further recites "a substantially uniform distribution of said desired amount of said active component within said polymer matrix, wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active in place within said matrix and maintain said substantially uniform distribution;"

   i. BDSI's BELBUCA buccal film literally infringes this limitation.

   ii. BDSI's BELBUCA buccal film contains buprenorphine hydrochloride as the active ingredient. *See* FDA Prescribing Information at 25.

iii. BDSI's BELBUCA buccal film uses BDSI's BEMA "delivery technology comprised of flexible, water soluble polymeric film." *See* Exhibit H, FDA Chemistry Review at 101.

iv. BDSI's BELBUCA buccal film contains a substantially uniform distribution of buprenorphine hydrochloride within the polymer matrix at least because, in approving BELBUCA, the FDA assessed the content uniformity of BELBUCA and found it sufficiently uniform. *See, e.g.*, Exhibit H, FDA Chemistry Review at 6.

v. At least as described in paragraphs 26 and 29 above, BDSI's BELBUCA buccal film is formed using a manufacturing process which involves mixing the ingredients together to make a flowable wet blend, and then casting the viscoelastic, wet blend of ingredients, the film matrix, onto a carrier which travels through an oven to dry the film into a sheet which is then cut into individual units, the specific details of which Aquestive has a good faith basis to believe will be shown by further discovery.

vi. At least as described in paragraphs 26, 28, 29, and 31 above, BDSI's BELBUCA buccal film manufacturing process maintains a high level of drug content uniformity by using a controlled drying process, one aspect of which is to form a polymeric matrix and lock the active component in place so that it minimizes migration so that it does not result in a disuniform film, the specific details of which Aquestive has a good faith basis to believe will be shown by further discovery.

e. Claim 95 further recites "wherein said film is self-supporting and the active component is substantially uniformly distributed, whereby said substantially uniform distribution is measured by

substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film is self-supporting at least because it is able to maintain its integrity and structure in the absence of a separate support when the film is removed from the foil package and applied directly against the cheek and left in place until the entire film dissolves. *See* FDA Prescribing Information at 30-31.

iii. BDSI's BELBUCA buccal film contains buprenorphine hydrochloride that is substantially uniformly distributed, whereby said substantially uniform distribution is measured by substantially equally sized individual unit does which do not vary by more than 10% of said desired amount of buprenorphine hydrochloride at least because, in approving BELBUCA, the FDA assessed the content uniformity of BELBUCA and found it sufficiently uniform. Aquestive has a good faith basis to believe that the specific content uniformity of BDSI's BELBUCA buccal film will be shown by further discovery. *See, e.g.*, Exhibit H, FDA Chemistry Review at 6.

44. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 96 of the '167 patent as follows:

a. Claim 96 recites "[t]he film of claim 95, further comprising a component selected from the group consisting of citric acid, propylene glycol, a sweetener, a preservative, a coloring agent, a flavor and combinations thereof."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 43, above.

iii. BDSI's BELBUCA buccal film contains citric acid anhydrous USP, propylene glycol USP, saccharin sodium NF, methylparaben NF, propylparaben NF, yellow iron oxide NF, black iron oxide NF, and peppermint oil NF. *See* FDA Prescribing Information at 25.

45. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 97 of the '167 patent as follows:

a. Claim 97 recites "[t]he film of claim 95 further comprising an opiate or opiate derivative."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 43, above.

iii. BDSI's BELBUCA buccal film contains buprenorphine hydrochloride. *See* FDA Prescribing Information at 25.

46. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 98 of the '167 patent as follows:

a. Claim 98 recites "[t]he film of claim 95 further comprising an analgesic."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 43, above.

iii. BDSI's BELBUCA buccal film contains buprenorphine hydrochloride. *See* FDA Prescribing Information at 25.

47. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 100 of the '167 patent as follows:

a. Claim 100 recites "[t]he film of claim 95 further comprising vitamin E acetate."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 43, above.

iii. BDSI's BELBUCA buccal film contains vitamin E acetate USP. *See* FDA Prescribing Information at 25.

48. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 101 of the '167 patent as follows:

a. Claim 101 recites "[t]he film of claim 95 further comprising titanium dioxide."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 43, above.

iii. BDSI's BELBUCA buccal film contains titanium dioxide USP. *See* FDA Prescribing Information at 25.

49. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 102 of the '167 patent as follows:

a. Claim 102 recites "[t]he film of claim 96 wherein the flavor comprises peppermint oil."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 96 of the '167 patent for the reasons identified in paragraph 44, above.

iii. BDSI's BELBUCA buccal film contains peppermint oil NF. *See* FDA Prescribing Information at 25.

50. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 103 of the '167 patent as follows:

a. Claim 103 recites "[t]he film of claim 95 further comprising a buffer."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 43, above.

iii. BDSI's BELBUCA buccal film contains monobasic sodium phosphate anhydrous USP and sodium hydroxide NF. *See* FDA Prescribing Information at 25.

51. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 107 of the '167 patent as follows:

a. Claim 107 recites "[t]he film of claim 96 wherein the sweetener comprises sodium saccharin."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 96 of the '167 patent for the reasons identified in paragraph 44, above.

iii. BDSI's BELBUCA buccal film contains saccharin sodium NF. *See* FDA Prescribing Information at 25.

52. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 108 of the '167 patent as follows:

a. Claim 108 recites "[t]he film of claim 95 further comprising polyacrylic acid."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 43, above.

iii. BDSI's BELBUCA buccal film contains polycarbophil USP. *See* FDA Prescribing Information at 25.

53. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 117 of the '167 patent as follows:

a. Claim 117 recites "[t]he film of claim 13, wherein the anti-tacking agent is present in an amount sufficient to impart reduced film-to-film coefficient of friction."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 34, above.

iii. BDSI's BELBUCA buccal film contains sodium benzoate NF. *See* FDA Prescribing Information at 25.

iv. At least as described in paragraphs 26, 27, 29, and 30 above, BDSI's BELBUCA buccal film contains sodium benzoate NF in an amount sufficient to impart reduced film-to-film coefficient of friction at least because BDSI's BELBUCA buccal film is manufactured in a manner where the film does not adhere to the film itself, the specific details of which Aquestive has a good faith basis to believe will be shown by further discovery.

54. Furthermore, BDSI's BELBUCA buccal film satisfies all elements of Claim 118 of the '167 patent as follows:

a. Claim 118 recites "[t]he film of claim 13, wherein the anti-tacking agent is present in an amount sufficient to yield a film with a coefficient of friction which reduces adhesion of the film to adjacent surfaces during processing."

i. BDSI's BELBUCA buccal film literally infringes this limitation.

ii. BDSI's BELBUCA buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 34, above.

iii. BDSI's BELBUCA buccal film contains sodium benzoate NF. *See* FDA Prescribing Information at 25.

iv. At least as described in paragraphs 26, 27, 29, and 30 above, BDSI's BELBUCA buccal film contains sodium benzoate NF in an amount sufficient to impart reduced film-to-film coefficient of friction at least because BDSI's BELBUCA buccal film is manufactured in a manner where the film does not adhere to adjacent surfaces during manufacturing, the specific details of which Aquestive has a good faith basis to believe will be shown by further discovery.

55. Aquestive reserves the right to further amend and/or supplement these allegations following BDSI's production of documents regarding BDSI's BELBUCA buccal film, BDSI's disclosure of any non-infringement or invalidity position, the Court's determination of the meaning of any disputed terms, and/or any other development in this litigation that would make such supplementation necessary or appropriate.

56. Aquestive has not granted a license to the '167 patent or given any other authority to BDSI—or to anyone else—to make, use, sell, and/or offer for sale BELBUCA.

57. According to its website and BDSI's financial filings, BDSI has received to date payments and milestones totaling at least $125 million to develop and make the infringing BELBUCA buccal film, and had net sales of BELBUCA buccal film of more than $115,000 from 2017 through June 2019.

58. BDSI's infringement of the '167 patent has caused and will continue to cause Aquestive irreparable injury and harm for which there is no adequate remedy

at law unless and until BDSI is permanently enjoined by this Court from infringing the '167 patent.

59. As a result of BDSI's infringing activities, Aquestive has suffered and will continue to suffer damages in an amount yet to be determined. Under 35 U.S.C. §§ 283 and 284, Aquestive is entitled to recover damages in an amount to be proven at trial, and in any event not less than a reasonable royalty, together with interests and costs, as well as permanent injunctive relief.

60. BDSI's infringement has been committed with full knowledge of Aquestive's rights in the '167 patent since at least (i) BDSI's first making, using, offering to sell, and/or selling BELBUCA or (ii) October 13, 2014. Such acts constitute willful and deliberate infringement, entitling Aquestive to enhanced damages and reasonable attorneys' fees.

COUNT 2:
Indirect Infringement of the '167 Patent

61. Aquestive incorporates each of the preceding paragraphs 1-60 as if fully set forth herein.

62. The use or administration of any of the dosage strengths of BDSI's BELBUCA buccal film by healthcare professionals and/or patients has directly infringed and continues to infringe at least the following valid and enforceable claims of the '167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118.

63. For at least the reasons identified in Paragraph 32-60 above, BDSI's BELBUCA buccal film meets all of the limitations of at least the following valid and enforceable claims of the '167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118.

64. Through its commercial manufacture, sale, offer for sale, and instructions for use of each of the dosage strengths of BDSI's BELBUCA buccal film and other actions, BDSI has indirectly infringed and continues to indirectly infringe under 35 U.S.C. §§ 271(b) and (c) at least the following valid and enforceable claims of the '167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118.

65. BDSI has had knowledge of the '167 patent since at least October 13, 2014, including knowledge of claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118 of the '167 patent.

66. BDSI has induced and continues to induce infringement of the '167 patent.

67. BDSI has induced and continues to induce infringement of the '167 patent by affirmatively aiding, abetting, urging, or encouraging direct infringement by healthcare professionals and/or patients, by, *inter alia*, instructing them to use BDSI's infringing BELBUCA buccal film. BDSI has explicitly instructed and continues to instruct healthcare professionals and/or patients to use its infringing BELBCUA buccal film by, *inter alia*, providing Prescribing Information and other instructions that instruct healthcare professionals and/or patients to use the

BELBUCA buccal film, which includes all of the elements of at least the following valid and enforceable claims of the '167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118.

68. Since at least October 13, 2014, BDSI has had knowledge that the induced acts would constitute infringement of the '167 patent and has specifically intended to cause such infringement. BDSI has, *inter alia*, intentionally provided Prescribing Information and other instructions to healthcare professionals and/or patients that instruction the healthcare professionals and/or patients to use the infringing BELBUCA buccal film, with knowledge of the '167 patent and with knowledge that use by the healthcare professional and/or patient of BELBUCA buccal film directly infringes at least the following valid and enforceable claims of the '167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118.

69. BDSI's affirmative acts, including its commercial manufacture, sale, offer for sale, and/or its provision of instructions for BELBUCA buccal film to healthcare professionals and/or patients have induced and/or caused, and continue to induce and/or cause, direct infringement by healthcare professionals and/or patients.

70. BDSI has contributed to, and continues to contribute to, infringement of at least the following valid and enforceable claims of the '167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118.

71. BDSI's BELBUCA buccal film constitutes a material part of the invention covered by the claims of the '167 patent because, *inter alia*, it includes all

of the elements of the oral films of at least claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118 of the '167 patent.

72. Since at least October 13, 2014, BDSI has known that its BELBUCA buccal film is especially made or especially adapted for use in the infringement of at least claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118 of the '167 patent.

73. Since at least October 13, 2014, BDSI has known that there is no substantial non-infringing use for its BELBUCA buccal film.

DEMAND FOR JUDGMENT

WHEREFORE, Aquestive requests the following relief:

1. A judgment that BDSI's making, using, offering to sell, and/or selling, within the United States, the accused BELBUCA film products infringes one or more claims of the '167 patent, in violation of 35 U.S.C. § 271(a);

2. A judgment that BDSI has actively induced others to infringe one or more claims of the '167 patent, in violation of 35 U.S.C. § 271(b);

3. A judgment that BDSI has contributed to others' infringement of one or more claims of the '167 patent, in violation of 35 U.S.C. § 271(c);

4. A judgment that BDSI has willfully infringed the '167 patent;

5. An award of damages adequate to compensate for BDSI's infringement of the claims of the '167 patent under 35 U.S.C. § 284, together with interest and costs as fixed by the Court;

6. An award of enhanced damages against BDSI for the willful infringement of the '167 patent;

7. A determination that this is an exceptional case within the meaning of 35 U.S.C.§ 285, and an award of Aquestive's reasonable attorneys' fees;

8. An injunction, pursuant to 35 U.S.C. § 283, permanently prohibiting BDSI from infringing any claims of the '167 patent prior to its expiration, including any extensions; and

9. Such other costs and further relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Aquestive requests a trial by jury on all triable issues.

Dated: November 11, 2019.

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